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21 UNITED STATES DISTRICT COURT
22 SOUTHERN DISTRICT OF CALIFORNIA

23 GEN-PROBE, INCORPORATED,)

24 Plaintiff,)

25 v.)

26 VYSIS, INC.,)

27 Defendant.)

Case No.: 99CV 2668H (AJB)

MEMORANDUM OF POINTS AND
AUTHORITIES IN SUPPORT
OF VYSIS MOTION TO FOR A STAY
PENDING COMPLETION OF REISSUE
PROCEEDINGS AND, ALTERNATIVELY,
TO DISMISS COUNT FOUR OF
THE FIRST AMENDED COMPLAINT
UNDER FED. R. CIV. P. 12(b)(6)

Date: April 10, 2000

Time: 10:30 a.m.

Place: Courtroom 1

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1 **CASES**

2	ASCII Corp. v. STD Entertainment USA, Inc., 844 F. Supp. 1378 (N.D. Cal. 1994)	3, 4
3	California Physicians' Service v. Superior Court, 9 Cal.App.4th 1321 (1992)	10
4	Cel-Tech Communications, Inc. v. Los Angeles Cellular Tel. Co., 20 Cal.4th 163 (1999)	10
5	Clintec Nutrition Co. v. Abbott Labs., No. 94-C3152, 1995 WL 228988, at *6 (N.D. Ill. Apr. 14, 1995)	3, 4, 5
6	Cordis Corp. v. Medtronic, Inc., 780 F.2d 991 (Fed. Cir. 1985)	9
7	Dennco, Inc. v. Cirone, No. 94-455-SD	5
8	Ethicon, Inc. v. Quigg, 849 F.2d 1422 (Fed. Cir. 1988)	3
9	Fisher Controls Co., Inc. v. Control Components, Inc., 443 F.Supp. 581 (S.D. Iowa 1977)	6
10	Gould v. Control Laser Corp., 705 F.2d 1340 (Fed. Cir. 1983)	6
11	GPAC, Inc. v. D.W.W. Enterprises, Inc., 144 F.R.D. 60 (D.N.J. 1992)	6, 7
12	Rubin v. Green, 4 Cal.4th 1187 (1993)	10, 11
13	Ryco Inc. v. Ag-Bag Corp. 857 F.2d 1418 (Fed. Cir. 1988)	9
14	Teradyne, Inc. v. Hewlett-Packard Co., No. 91-C-0344, 1993 U.S.Dist. LEXIS at *21 (N.D. Cal. Jan. 7, 1993)	4
15	Triplett v. Farmers Ins. Exchange, 24 Cal.App.4th 1415 (1994)	11
16	United Merchants Mfrs., Inc., 495 F.Supp.444 N.D.Ga. 1980)	6, 7
17	United Sweetener USA, Inc. v. Nutrasweet Co., 766 F.Supp. 212 (D. Del. 1991)	4, 7

25 **STATUTES**

26	35 U.S.C. § 1.176	2
27	35 U.S.C. § 251	2
28	35 U.S.C. § 282	9

1	37 Code of Federal Regulations § 1.291	4, 5
2	Cal. Bus. & Prof. Code § 17200 et seq.	1, 8
3	California Civil Code § 47(b)	10
4	Fed. R. Civ. P. 12(b)(6)	2, 8, 11

OTHER

7	Manual of Patent Examining Procedure § 1442	4, 5
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1 I. INTRODUCTION

2 Effective June 22, 1999, Gen-Probe Incorporated ("Gen-Probe")
3 took a license under Vysis', Inc.'s United States Patent No.
4 5,750,338 ("the '338 patent"). See First Amended Complaint ¶ 20. On
5 December 22, 1999, Gen-Probe filed a Complaint against Vysis,
6 requesting this Court to declare the '338 patent 9 (Ex. A)¹ invalid
7 and not infringed by Gen-Probe's Nucleic Acid Test "NAT" kits. On
8 January 6, 2000 (at Vysis' request), Gen-Probe identified six
9 technical publications that it contended invalidated the '338 patent
10 (Ex. B). None of these publications appears to describe processes
11 where nucleic acid targets are first separated from a patient sample
12 and then subjected to an in vitro amplification process where many
13 copies of each target molecule are made. This was the focus of all
14 of the examples of the '338 patent, and of the United States Patent
15 and Trademark Office ("PTO") in deciding to issue the '338 patent.
16 It is also an essential feature of Gen-Probe's "NAT" test kits. On
17 January 19, 2000, Vysis (at Gen-Probe's request) informed Gen-Probe
18 that it would answer the Complaint in this action (Ex. C).

19 In response, on January 25, 2000, Gen-Probe filed a First
20 Amended Complaint again requesting the Court to declare the '338
21 patent invalid and not infringed by Gen-Probe's NAT test kits, and,
22 additionally, to declare Gen-Probe's rights and obligations under the
23 License between Gen-Probe and Vysis pertaining to the '338 patent
24 (pertinent portions of which are attached as Ex. D), and charging
25 Vysis with unfair competition and violation of Cal. Bus. & Prof. Code
26 § 17200 et seq. See First Amended Complaint, Count Four.

27
28 ¹All exhibits referred to in this memorandum are attached to and
authenticated by the Declaration of John H. L'Estrange, Jr. filed this same
date.

1 In an effort to secure a speedy, inexpensive and just resolution
2 of the patent validity issues raised by Gen-Probe, Vysis filed on
3 March 8, 2000, an application with the PTO to reissue the '338 patent
4 under 35 U.S.C. § 251 (Ex. E). Vysis identified the publications
5 cited by Gen-Probe for the PTO so that their effect, if any, on the
6 existing claims may be determined. Additionally, Vysis has presented
7 narrower claims that clearly avoid Gen-Probe's publications yet still
8 clearly cover Gen-Probe's products.

9 As more fully set forth in Section II below, this action should
10 be stayed pending the outcome of the reissue proceedings² so that the
11 Court and the parties may have the benefit of the PTO's views on the
12 issues raised by Gen-Probe and so that any newly issued patent claims
13 can be made a part of this action.

14 Alternatively, for reasons noted in Section III below, Gen-
15 Probe's claim for unfair competition should be dismissed under Fed.
16 R. Civ. P. 12(b)(6) as failing to state a claim upon which relief can
17 be granted. If the motion for a stay is granted the Rule 12(b)(6)
18 motion to dismiss Count Four may be deferred until after the stay is
19 vacated by the Court.

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26 ²Reissue is essentially a prosecution of the patent. The patentee may
27 include for examination in the reissue application: (i) unchanged, original
28 claims; (ii) new, narrower claims; and (iii) if the reissue is filed within two
years of the grant of the patent, new, broader claims. A reissue application is
examined in the same manner as original applications; original claims may
therefore be rejected, and new claims may be allowed. See 35 U.S.C. § 1.176.

1 II. THE LITIGATION SHOULD BE STAYED PENDING RESOLUTION OF REISSUE
2 PROCEEDINGS FOR THE '338 PATENT

3 Gen-Probe alleges that the '338 patent is invalid. Specifically,
4 at paragraph 23 of its First Amended Complaint, Gen-Probe asserts
5 that:

6 23. Gen-Probe has communicated to Vysis its belief
7 that the claims of the '338 patent are invalid. In
8 support of that belief, Gen-Probe has provided Vysis
9 with information that demonstrates that the claims of
10 the '338 patent are invalid.

11 Vysis believes that the information that Gen-Probe has cited
12 does not invalidate the '338 patent. However, in the interests of
13 judicial economy, Vysis has requested the PTO to reissue the '338
14 patent. Specifically, Vysis has asked the PTO to allow additional,
15 narrower claims, which clearly avoid the art cited by Gen-Probe and
16 which still cover Gen-Probe's activities. In doing so, the PTO will
17 review the '338 patent in view of the information which Gen-Probe has
18 provided to Vysis. To avoid substantial duplication of effort in
19 determining the patent's validity, and to avoid potentially wasted
20 investment in analyzing claims for infringement (a) which may or may
21 not be altered during reissue, and (b) which may come into existence
22 only following the reissue process, Vysis moves this court to stay
23 the litigation proceedings pending the outcome of the reissue
24 proceedings in the PTO.

25 Granting a stay is well within the Court's discretionary power
26 to manage its docket. *Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1426-27
27 (Fed. Cir. 1988) Courts routinely grant stays during reissue
28 applications for just this purpose. *Clintec Nutrition Co. v. Abbott
Labs.*, No. 94-C3152, 1995 WL 228988, at *6 (N.D. Ill. Apr. 14, 1995)
(motion to stay pending outcome of reissuance proceedings granted);
see also *ASCII Corp. v. STD Entertainment USA, Inc.*, 844 F. Supp.

1 1378, 1380-81 (N.D. Cal. 1994) (The court has the inherent ability to
2 grant a stay of proceedings; motion to stay pending outcome of
3 reexamination or reissue proceedings granted).

4 In deciding a motion to stay, courts generally consider: (a)
5 whether doing so would cause undue prejudice or present a clear
6 tactical disadvantage to the non-moving party (*ASCII*, 844 F.Supp. at
7 1380); and (b) whether the stay will result in a simplification or a
8 complication of the issues, proof and questions of law (*Clintec*, 1995
9 WL at *1 (citing, *Teradyne, Inc. v. Hewlett-Packard Co.*, No. 91-C-
10 0344, 1993 U.S. Dist. LEXIS at *21 (N.D. Cal. Jan. 7, 1993)). In this
11 matter, the Court's consideration of whether to grant a stay should
12 also be informed by the terms and purposes of the Declaratory
13 Judgment Act. See *United Sweetener USA, Inc. v. Nutrasweet Co.*, 766
14 F.Supp. 212, 215-16 (D. Del. 1991). All factors weigh in favor of a
15 stay.

16 **A. A Stay Would Not Cause Undue Prejudice To Gen-Probe**

17 A stay would not cause undue hardship because (a) little
18 investment has been made by either party in this litigation; (b)
19 reissue proceedings are "special" (*Manual of Patent Examining*
20 *Procedure* (hereinafter "MPEP"), § 1442) and thus the PTO expedites
21 their processing (MPEP § 1442,03); and (c) Gen-Probe can file a
22 protest in the PTO expressing its views on the validity of the '338
23 patent (37 C.F.R. § 1.291).

24 With respect to the interest of the parties in the current
25 litigation, the action is barely a few months old, Vysis has not
26 answered the complaint, there has been no Early Neutral Evaluation
27 Conference, neither party has responded to discovery requests, a pre-
28 trial order has not been submitted and will not be submitted for some
time, and a trial date has not been set. See *ASCII*, 844 F.Supp at

1 1381 (no undue prejudice and motion to stay granted where parties
2 were only in initial stages of lawsuit, undertaken little or no
3 discovery, and case had not been set for trial); *Dennco, Inc. v.*
4 *Cirone*, No. 94-455-SD (no undue prejudice and motion to stay granted
5 where the parties were in the initial stages of the lawsuit and had
6 undertaken little or no discovery); *Clintec*, 1995 WL, at *3 (no undue
7 prejudice and motion to stay granted where suit was filed about one
8 year prior, two depositions had been taken, some paper discovery had
9 occurred, but no trial date was set).

10 Reissue proceedings would not cause undue hardship for the
11 further reason that the PTO expedites the processing of such
12 applications, placing great emphasis on the expedited processing of
13 reissue applications which are the subject of a stayed litigation.
14 MPEP § 1442.03. All reissue applications are taken up "special", and
15 are also taken up ahead of all other "special" applications. MPEP §
16 1442. Special applications are responded to immediately. Id.
17 Finally, unlike other applications for which applicants have up to
18 six months to respond to PTO actions, reissue applicants only receive
19 one month to respond to PTO actions and this time period may be
20 extended only upon a showing of clear justification. MPEP § 1442.01;
21 37 C.F.R. 1.136(b). Finally, grant of stay pending resolution of the
22 reissue proceedings will not cause undue prejudice because Gen-Probe
23 can provide the PTO with its view on the validity of the '338 patent
24 through an appropriate protest. 37 C.F.R. § 1.291; MPEP § 1901.

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1 B. A Stay Would Result In A Simplification
2 Of The Issues, Proof, And Questions Of Law

3 A stay would serve the interests of judicial economy. Patent
4 validity, a core issue in the reissue proceeding, is also a central
5 issue in this litigation. Grant of a stay would serve the interests
6 of judicial economy by preventing the substantial duplication of
7 effort that would occur if this case proceeded conjunctively with the
8 reissue proceeding. See *GPAC, Inc. v. D.W.W. Enterprises, Inc.*, 144
9 F.R.D. 60, 64, (D.N.J. 1992). In addition, by shifting to the PTO
10 the initial decision on patent validity, the outcome of the reissue
11 proceeding would facilitate settlement without further use of the
12 court. See *id.*; *United Merchants Mfrs., Inc.*, 495 F.Supp.444,447
13 (N.D.Ga. 1980); *Fisher Controls Co., Inc. v. Control Components,*
14 *Inc.*, 443 F.Supp. 581, 582 (S.D. Iowa 1977) At worst, the litigation
15 would proceed afterwards with the court having the benefit of the
16 PTO's expertise in evaluating validity in view of prior art
17 references. In this regard, a stay will minimize the prospect of the
18 Court having to deal with validity defenses that have not been
19 initially passed upon by the PTO. See *GPAC*, 144 F.R.D. at 65; see
20 also *ASCII*, 844 F.Supp. at 1381 ("[T]he court concludes that ASCII
21 should be given the opportunity to file an application for
22 reexamination and/or reissue, since the USPTO's expertise may assist
23 both the parties and the court. . . ."); *Gould v. Control Laser*
24 *Corp.*, 705 F.2d 1340, 1342 (Fed. Cir. 1983) ("One purpose of the
25 reexamination [or reissue] procedure is . . . to facilitate trial of
26 [validity] by providing the district court with the expert view of
the PTO. . . .").

27 Additional benefits of a stay which courts have recognized, and
28 are applicable to the case at hand, include: (a) Many discovery

1 problems relating to the prior art can be alleviated by the PTO
2 examination; (b) The record of reissue would likely be entered at
3 trial, thereby reducing the complexity and length of the litigation;
4 (c) Issues, defenses, and evidence will be more easily limited in
5 pre-trial conferences after a reissue; and (d) The cost will likely
6 be reduced both for the parties and the court. See *GPAC*, 144 F.R.D.
7 at 63; *Clintec*, 1995 WL, at *2; *United Merchants and Mfrs.*, 495
8 F.Supp. at 447; *Fisher Controls Co., Inc.*, 443 F.Supp. at 582.

9 **C. A Stay Is Particularly Appropriate**

10 **In A Declaratory Judgment Proceeding**

11 The Declaratory Judgment Act is an authorization for
12 jurisdiction, not a command. *United Sweetener*, 766 F.Supp. at 216
13 (quoting *Erbamont, Inc. v. Cetus Corp.*, 720 F.Supp. 387, 392 (D. Del.
14 1990)). Under the Act, courts should refuse to proceed if they find
15 that a declaratory judgment action will not serve a useful purpose or
16 is otherwise undesirable. *United Sweetener*, 766 F.Supp. at 216
17 (quoting *Erbamont, Inc. v. Cetus Corp.*, 720 F.Supp. 387, 392 (D. Del.
18 1990)). In determining the appropriateness of a declaratory judgment
19 action, courts should consider whether such an action would clarify
20 and settle the legal relations in issue, and whether such an action
21 would terminate and afford relief from the uncertainty, insecurity,
22 and controversy giving rise to the action.

23 As discussed above, staying this litigation in favor of the PTO
24 proceedings would simplify issues and evidence and may moot the
25 litigation altogether by promoting settlement. Accordingly, it would
26 be entirely consistent with the discretionary nature of declaratory
27 judgment jurisdiction to condition the exercise of that jurisdiction
28 on a stay pending completion of the reissue proceedings.

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1 In this regard, Vysis respectfully requests that Gen-Probe be
2 ordered to timely answer Vysis' First Set of Interrogatories, served
3 January 26, 2000, (Ex. F), notwithstanding the entry of the stay.
4 Those interrogatories simply seek the bases for Gen-Probe's
5 allegations of invalidity and noninfringement. The answers are
6 necessary for the Court and the parties to gain the full benefit of
7 the reissue proceedings. Gen-Probe's letter informing Vysis of the
8 publications allegedly invalidating the '338 patent explicitly stated
9 that there are other such materials of which Gen-Probe is aware (Ex.
10 B). If there are additional validity or claim interpretation issues
11 now known to Gen-Probe, Gen-Probe should identify them so that the
12 PTO's reissue procedures can be as complete as possible. The
13 discovery request was timely served and, but for Gen-Probe's request
14 for an extension of time to answer in exchange for the extension
15 granted Vysis to respond to the amended complaint, would already have
16 been answered.³

17 **III. THE UNFAIR COMPETITION CLAIM SHOULD BE**
18 **DISMISSED UNDER FEDERAL RULE OF**
19 **CIVIL PROCEDURE 12(b) (6)**

20 Vysis respectfully moves the Court, in the alternative, for an
21 order dismissing Gen-Probe's unfair competition allegations set forth
22 in Count Four of the First Amended Complaint for failure to state a
23 claim for which relief can be granted. Fed. R. Civ. P. 12(b)(6).
24 The alleged act of unfair competition is stated in paragraph 35 of
25 the First Amended Complaint as follows:

26 35.Vysis knows or should know the underlying facts
27 establishing the invalidity of the claims of the '338
28 patent. In continuing to enforce the claims of the '338

³This Court's Order dated February 8, 2000, requires Gen-Probe to respond by March 27, 2000.

1 patent, Vysis has acted and continues to act unfairly,
2 inequitably and in bad faith. In addition, Vysis' actions
3 constitute unlawful, unfair or fraudulent business
practices under California Business & Professions Code
Sections 17200, et seq.

4 The apparent antecedent for the acts of "continuing to enforce
5 the claims of the '338 patent" is stated in paragraphs 23 and 24 as
6 follows:

7 23. Gen-Probe has communicated to Vysis its belief that
8 the claims of the '338 patent are invalid. In support of
9 that belief, Gen-Probe has provided Vysis with information
10 that demonstrates that the claims of the '338 patent are
invalid. Gen-Probe has also advised Vysis of its belief
that its NAT test kits for use in detecting HCV and HIV in
the Nation's blood supply do not and will not infringe any
valid claims of the '338 patent.

11 24. Notwithstanding its receipt of the foregoing
12 information, Vysis persists in its assertion that the
13 claims of the '338 patent are valid and enforceable and
that Gen-Probe is obligated to make royalty payments in
accordance with the terms of the License.

14 Gen-Probe does not allege that the license contract is not a
15 valid contract. The contract provides that royalties shall be paid
16 unless and until a licensed patent claim is declared invalid in a
17 final decision from a tribunal of competent jurisdiction. This is in
18 accord with the substantive patent law, which provides that (a) a
19 patent is presumed valid (35 U.S.C. § 282); (b) the party asserting
20 invalidity has the burden of proving that the patent is invalid by
21 clear and convincing evidence (*Ryco Inc. v. Ag-Bag Corp.* 857 F.2d
22 1418, 1423 (Fed. Cir. 1988)); and (c) a licensee wishing to retain
23 the benefits of a patent license must continue to pay royalties until
24 the presumptively valid patent is declared invalid (*Cordis Corp. v.*
25 *Medtronic, Inc.*, 780 F.2d 991, 994-95 (Fed. Cir. 1985)). Thus,
26 Vysis' alleged persistence in its belief that the patent remains
27 valid and enforceable and that Gen-Probe is obligated to make royalty
28 payments in accordance with the terms of the license is simply

1 declaratory of Gen-Probe's obligations under a valid contract.
2 Section 17200 cannot convert activity authorized by law into a tort.
3 *Cel-Tech Communications, Inc. v. Los Angeles Cellular Tel. Co.*, 20
4 Cal.4th 163, 182 (1999).

5 Moreover, the license contract may be terminated unilaterally by
6 Gen-Probe in accordance with the terms of the agreement (Ex. D).
7 Vysis cannot, therefore, be forcing Gen-Probe to be a licensee or to
8 perform any of the obligations under the license contract.

9 If the asserted invalidity or noninfringement of the '338 patent
10 is as clear as Gen-Probe would have this Court believe, Gen-Probe may
11 terminate the license, thereby freeing itself from its royalty
12 obligations thereunder. If, on the other hand, the outcome of its
13 declaratory judgment action on validity and infringement of the '338
14 patent is sufficiently unclear that Gen-Probe wishes to maintain its
15 rights under the license in the event of an adverse judgment, then
16 the continued existence of the license agreement, with the associated
17 obligation to abide by its terms, can hardly constitute an act of
18 unfair competition. The decision of whether or not to remain a
19 licensee is entirely Gen-Probe's. Gen-Probe cannot blame Vysis for
20 the logical consequences of Gen-Probe's unilateral decision to remain
21 a licensee.

22 Finally, if Gen-Probe is implying that Vysis' decision to defend
23 itself in this lawsuit is the act of "enforcement" constituting
24 unfair competition, this action is specifically authorized under the
25 litigation privilege of California Civil Code § 47(b) and cannot,
26 therefore, constitute unfair competition. *Cel-Tech*, 20 Cal.4th at
27 182-3 (referring to *Rubin v. Green*, 4 Cal.4th 1187 (1993)); see also
28 *California Physicians' Service v. Superior Court*, 9 Cal.App.4th 1321,
1325 (1992) ("[t]here is no tort of 'malicious defense.' The

1 mainstay supporting this principle is the absolute privilege
2 contained in Civil Code section 47, subdivision (b).") (1992). The
3 only exception to California's litigation privilege under Section
4 47(b) is malicious prosecution. Rubin, 4 Cal.4th at 1193-94,
5 However, Gen-Probe cannot allege malicious prosecution for at least
6 two reasons. First, Vysis is defending this action, not prosecuting
7 it, and as noted, no tort for "malicious defense" exists. *Triplett*
8 *v. Farmers Ins. Exchange*, 24 Cal.App.4th 1415, 1422 (1994). Second,
9 to prove malicious prosecution, Gen-Probe needs to show favorable
10 termination of the underlying action, which it cannot do, or even
11 plead, prior to resolution of its declaratory judgment action on the
12 patent validity and liability issues.

13 In view of the foregoing, Gen-Probe's unfair competition claims
14 should be dismissed under Fed. R. Civ. P. 12(b)(6) for failure to
15 state a claim upon which relief can be granted.

16 IV. CONCLUSION

17 For the reasons discussed above, Vysis respectfully requests
18 that this Court grant its motion to stay in this litigation, pending
19 the outcome of the reissue proceedings at the PTO (with the exception
20 that Gen-Probe be required to timely respond to the first set of
21 interrogatories served by Vysis); and, alternatively, to dismiss

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Count Four of the First Amended Complaint for failure to state a claim for which relief can be granted.

Respectfully submitted,